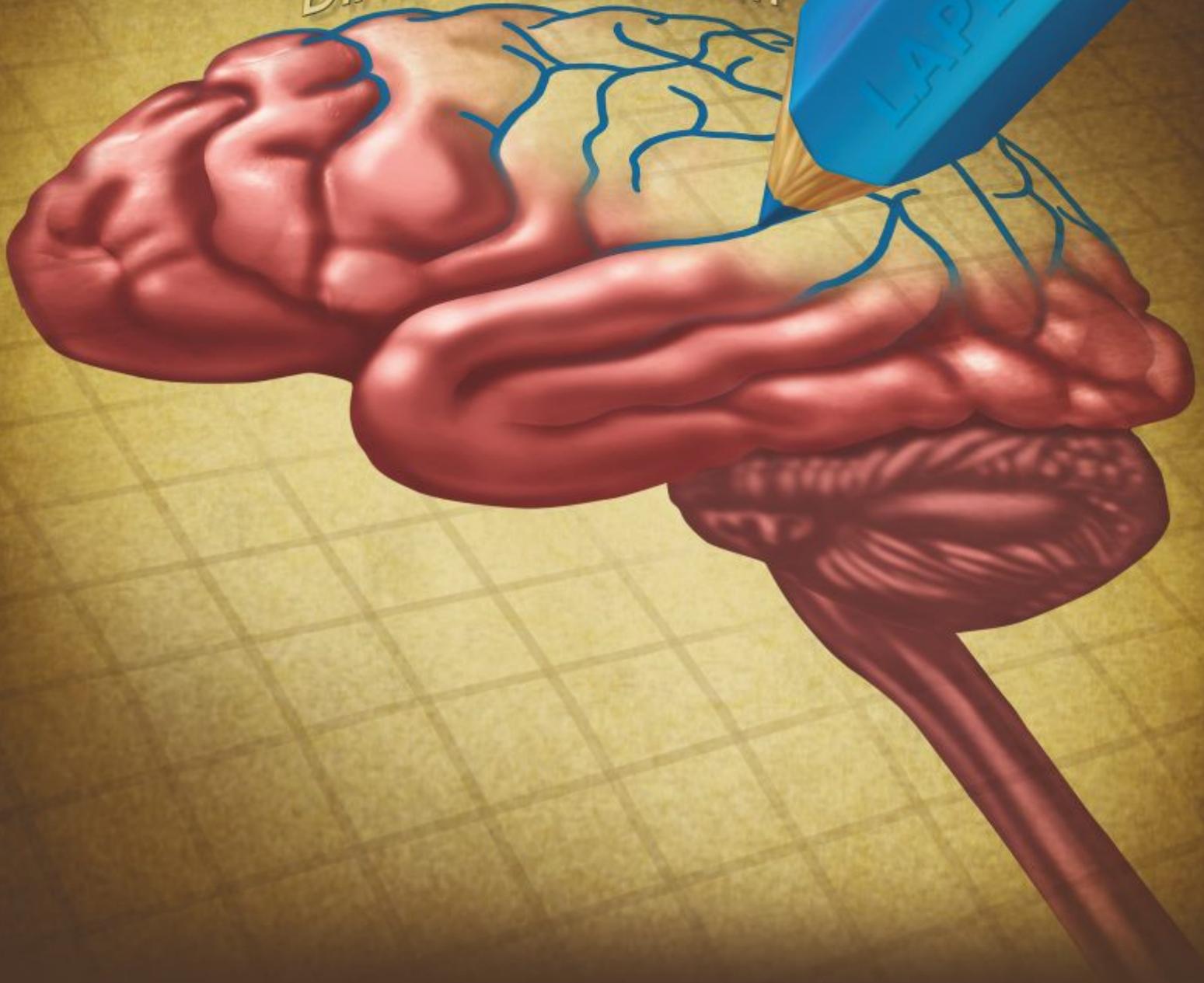


La Renon

Restore the  
DIMMING MEMORY



# LAPEZIL

Donepezil 5 mg and 10 mg Tablets

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## BACKGROUND:

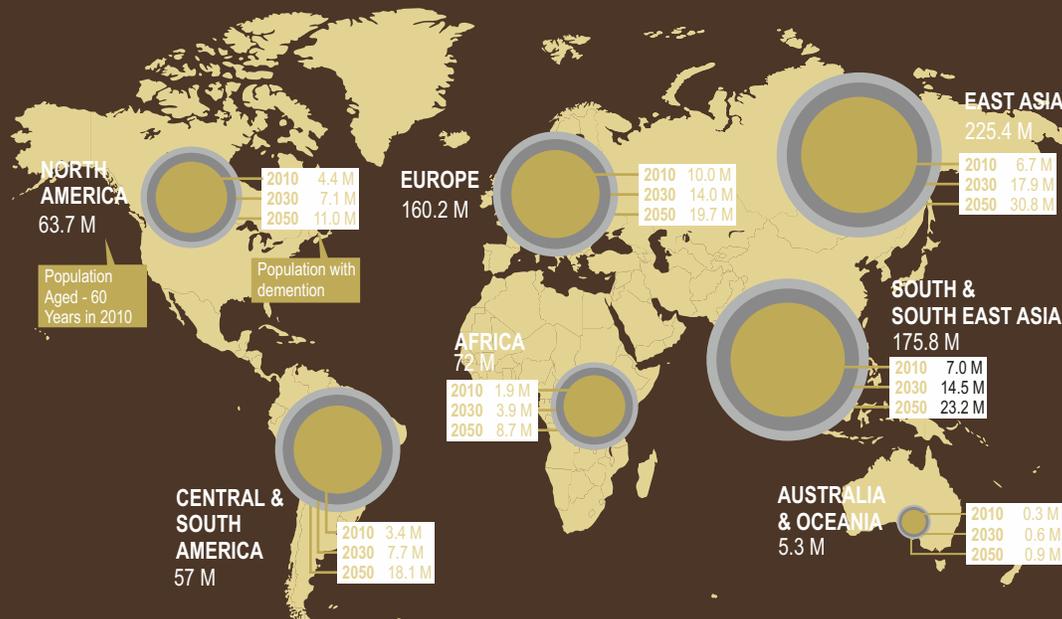
- Alzheimer's disease is the most common cause of dementia. The word dementia describes a set of symptoms that can include memory loss and difficulties with thinking, problem-solving or language. These symptoms occur when the brain is damaged by certain diseases, including Alzheimer's disease.
- Alzheimer's disease, named after the doctor who first described it (Alois Alzheimer), is a physical disease that affects the brain. During the course of the disease, proteins build up in the brain to form structures called 'plaques' and 'tangles'. This leads to the loss of connections between nerve cells, and eventually to the death of nerve cells and loss of brain tissue. People with Alzheimer's also have a shortage of some important chemicals in their brain. These chemical messengers help to transmit signals around the brain.
- When there is a shortage of them, the signals are not transmitted as effectively.
- Alzheimer's is a progressive disease. This means that gradually, over time, more parts of the brain are damaged. As this happens, more symptoms develop. They also become more severe.<sup>1</sup>

## PREVALENCE:

- Alzheimer's disease is the 6<sup>th</sup> leading cause of DEATH in the United states.
- Worldwide, 47.5 million people have dementia and there are 7.7 million new cases every year.<sup>2</sup>
- Alzheimer's disease is the most common cause of dementia and may contribute to 60–70% of cases.
- 1 in 3 seniors dies with Alzheimer's or another dementia.
- Among people age 70, 60% of those with Alzheimer's are expected to die before age 80 compared with 30% of those without Alzheimer's.

## ESTIMATED GROWTH OF DEMENTIA:

The number of people with dementia will roughly double every 20 years, with the biggest increase in developing countries.



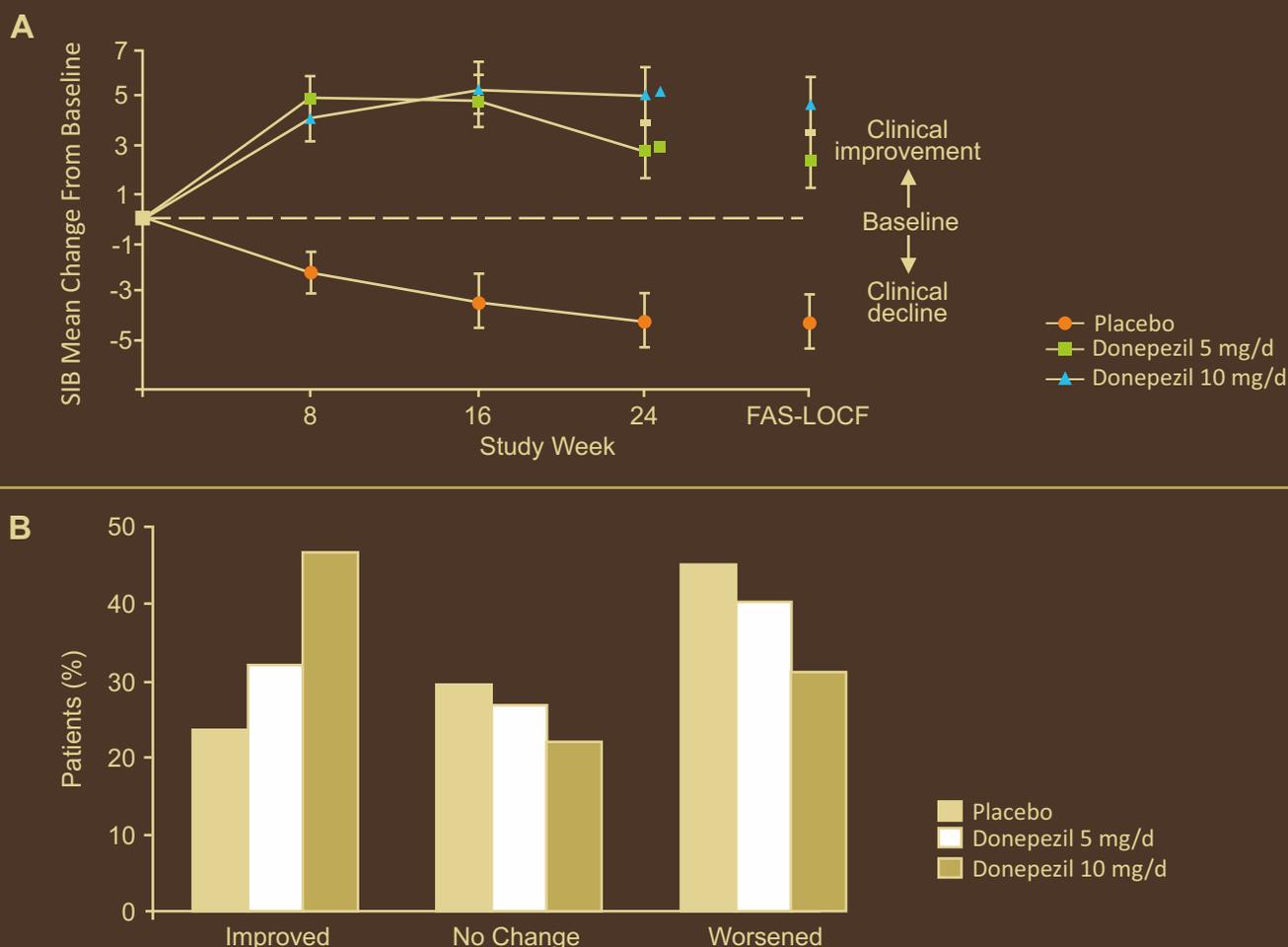
## CLINICAL EFFECTIVENESS:

As per *American Journal of Alzheimer's disease & other Dementias*; 2009

A 24-week, randomized, parallel-group, double-blind placebo-controlled study conducted to evaluate the efficacy and tolerability of donepezil in severe Alzheimer's disease (AD).

## RESULTS:

- Donepezil 5 mg/day and 10 mg/day were significantly superior to placebo on the SIB, with a least-squares mean treatment difference of 6.7 and 9.0, respectively ( $p < 0.001$  compared with placebo).
- CIBIC-plus analyses showed significant differences in favor of Donepezil 10 mg/day over placebo at endpoint ( $p = 0.003$ ).



**Figure:** Japanese study. **A**, Effect of donepezil treatment on Severe Impairment Battery (SIB) scores; error bars represent SE of the mean; data are for observed cases at weeks 8, 16, and 24, and for the FAS population at endpoint (LOCF); \* $P < .001$  versus placebo. **B**, Effect of donepezil treatment on Clinician's Interview-Based Impression of Change-plus caregiver interview (CIBIC-plus) scores (3-category collapsed analysis). FAS-LOCF - full analysis set-last observation carried forward; ITT - intent to treat.

## CONCLUSION:

- Donepezil has strong efficacy data in AD from the mild to the severe stage and has been shown to be effective for treating all domains of AD.
- Donepezil has consistent data throughout the AD spectrum from patients with mild AD through to severe AD, even when initiated in severe AD.

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## INDICATION:

LAPEZIL is an acetylcholinesterase inhibitor indicated for the treatment of dementia of the Alzheimer's type. LAPEZIL is effective in patients with mild, moderate, and severe Alzheimer's disease.

## COMPOSITION:

Donepezil Hydrochloride: 5 mg & 10 mg

## MECHANISM OF ACTION:

LAPEZIL (donepezil hydrochloride) is a reversible inhibitor of the enzyme acetylcholinesterase, known chemically as (±)-2, 3-dihydro-5, 6-dimethoxy 2-[[1-(phenylmethyl)-4-piperidiny] methyl]-1H-inden-1-one hydrochloride.

Recent theories on the pathogenesis of the cognitive signs and symptoms of Alzheimer's disease attribute some of them to a deficiency of cholinergic neurotransmission. It is suggested that Donepezil hydrochloride, exert its therapeutic effect by enhancing cholinergic function. This is accomplished by increasing the concentration of acetylcholine through reversible inhibition of its hydrolysis by acetylcholinesterase. There is no evidence that donepezil alters the course of the underlying dementing process.

## DOSAGE:

Mild to Moderate Alzheimer's disease: The dosages of LAPEZIL are 5 mg and 10 mg administered once per day.

Moderate to Severe Alzheimer's disease: LAPEZIL has been shown to be effective in Moderate to Severe Alzheimer's Disease at doses of 10 mg administered once daily.

## ADMINISTRATION:

LAPEZIL should be taken in the evening, just prior to retiring.

LAPEZIL can be taken with or without food.

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